Add new claims 22-26 as follows: - -

22. The device of claim 4, wherein the absorbent material comprises cellulose.

23. The device of claim 4, wherein the absorbent material comprises glass fiber and cellulose.

24. The kit of claim 19 wherein said kit further comprises packaging means for transporting the collected sample.

25. The device of claim 1, wherein said strip is made of a polymer and is rigid enough to prevent drooping or bending of the strip during manipulation by a user of the device.

26. The device of claim 25, wherein said polymer is polystyrene.- -

REMARKS

Applicants have developed a device for both collecting and drying a liquid biological sample at a first location, and then mailing the dried sample to a clinical laboratory remotely located from the first location for analysis. A preferred version of Applicants' device includes a strip having a handle end and a collection end. The handle end can be used for manipulating the device during the sample collection step (e.g., manually placing the device into a urine stream or dipping the device into a collection cup containing a urine sample). Attached to the collection

end of the strip is a collection pad for collecting a liquid sample. The collection pad is made of a material that can (a) absorb the liquid sample and (b) allow the liquid sample to dry in a relatively short period. The device also includes a means for facilitating removal of at least a portion of the collection pad from the strip. Because the device is used with dry samples, among other things, it advantageously provides (a) increased sample stability especially to the higher temperatures encountered in mailing (b) lighter weight requiring less postage, (c) significantly reduced risk of accidental leakage during transport (a dried sample being less likely to leak than a liquid sample), and (d) rapid removal of the sample from the device to facilitate analysis at the clinical laboratory.

Claim Status

Claims 1-12 and 19-21 were pending in the application. In view of Applicants' amendment filed July 11, 2000, all rejections made in the prior office action (mailed April 12, 2000) were withdrawn. In the present Office Action, all of the pending claims were rejected in view of newly cited art. Upon entry of this Amendment, claims 1-7, 19, and 20 will have been amended and new claims 22-26 added. Therefore, claims 1-12 and 19-26 will be pending. Entry of this Amendment and consideration of these claims is respectfully requested.

Rejection Under 35 U.S.C. 112 Second Paragraph

In the Office Action, claims 1 and 19 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Office Action indicated that

Claims 1 and 19 contain the phrase "relatively rigid strip". It is unclear as to what Applicants intend by "relatively rigid".

As indicated in new claim 25, Applicants intended the phrase "relatively rigid" to mean being "rigid enough to prevent drooping or bending of the strip during manipulation by a user of the device." Specification at page 9, lines 20-22. Nonetheless, Applicants have rendered this rejection moot by herewith amending claims 1 and 19 to remove recitation of the phrase "relatively rigid." Accordingly, withdrawal of this rejection is respectfully requested.

U.S. Patent 5,609,160 to Bahl et al.

The Office Action rejected all of the pending claims in view of U.S. Patent 5,609,160 to Bahl et al (hereinafter "Bahl"). Bahl discloses a sample collection device for collecting an oral fluid sample and transporting the collected liquid sample to a testing laboratory for analysis. Bahl does not disclose a device for both collecting and drying a liquid sample. Nor does Bahl describe a device for collecting biological samples apart from oral fluids.

In the detailed description, Bahl describes a sample collection device that includes a pad made of medical grade 100% pure cotton. Col. 3, lines 40-49 The pad has no chemicals added to it, and is used by placing it in a patient's mouth until a volume of between 0.75 to 1.2 ml of oral fluid is collected.

Bahl also describes a pouch into which the sample collection device can be placed. Col. 4, line 56- Col. 5, line 9. Bahl's pouch is flexible and impermeable and holds a preservative. The pouch has a series of temporary seals, including an upper seal that breaks when the user inserts the sample collection device into the pouch, such that the pad becomes "bathed with

preservative which will stabilize the sample until it reaches the lab." Col. 5, lines 3-5. The sample collected by Bahl's device is therefore never allowed to dry on the pad.

The pouch is surrounded by a leak-free rigid or semi-rigid container, and is designed to be mailed to a reference laboratory. Upon receipt by the reference lab, to collect the liquid sample for analysis, "the entire mailer or the leak-proof container, including the pouch and collection stick, will be removed from the mailer and centrifuged." Col. 6, lines 6-14. Because the sample remains a liquid throughout the collection and transport processes, the centrifugation step allows the sample to be removed from the pad without removing the pad from the collection device.

Rejection Under 35 U.S.C. § 102

In the Office Action, claims 1, 4, 5, 7, 8, 10, and 19-21 were rejected under 35 U.S.C. § 102(b) as being anticipated by Bahl. More specifically, the Office Action stated:

> Bahl et al '160 teach a fluid sample collection device comprising a plastic frame having a handle end (30, 40) and a collection end. The device contains an absorbent cotton (cellulosic) pad (50) for collecting the sample. There are openings (32, 42) through the collection end of the device such that the absorbent pad is exposed and capable of collecting the sample. The device also contains an additional opening (28) which allows the oral sample to be extracted during centrifugation. At col. 4, lines 8-14, Bahl et al '160 disclose that a portion of the absorbent pad is treated with an indicator (dye) such that when sufficient fluid is taken up by the pad, a change in color occurs. Also provided are a package for return of the sample by mail, and an identification card (90) containing information for identifying the sample. See figures 1 and 10.

Regarding rejections under 35 USC 102, the Federal Circuit has held that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Amended claims 1 and

19, from which all the rejected claims ultimately depend, include at least two claim elements not found in Bahl. First, amended claims 1 and 19, include a "collection pad for collecting and drying" a sample. Second, amended claims 1 and 19, include "a means for facilitating removal of at least a portion of the collection pad from the strip to recover the analyte for detection or measurement by laboratory analysis."

In contrast to the claimed invention, Bahl's device does not dry a liquid sample. It thus does not contain components suitable (a) for drying a liquid biological sample or (b) for removing a portion of the collection pad from the device (Bahl removes the sample using centrifugation not removal of the pad from the device). Accordingly, independent claims 1 and 19 as well as claims 2-12 and 20-26 that ultimately depend from claims 1 or 19, are not anticipated by Bahl.

Applicants also point out, that many of the dependent claims contain other limitations not taught by Bahl. For example, prior to entry of this Amendment, claim 8 recited a collection pad that is "pre-treated" with a reagent. The Office Action did not explain the basis for this rejection, and nowhere does Bahl refer to pre-treatment of a collection with a reagent. In fact, to the contrary, Bahl explicitly indicates that his pad for collecting an oral fluid has no chemicals added to it. Col. 3, lines 40-41 and lines 52-55.

In addition, regarding claim 19, Applicants submit that Bahl's identification card 90 is not equivalent to claim 19's "information card for providing information about the patient." Bahl's card apparently contains thereon a toll-free telephone number that the user can call to access the test results. After calling the toll-free number, the user provides the unique sample identification number 92 (apparently on the card 90 as well), so that this number can be matched

with the identification number 22 on the device 20 at the laboratory. Nothing on Bahl's identification card provides any "information about the patient." Examples of information about a patient are described in Applicants' specification at page 17, lines 8-9, as "...e.g., medical history or health status of the individual being tested for disease or metabolic disorder." As Bahl's "identification" card is not equivalent to claim 19's "information" card, Applicants submit that this rejection is improper and should be withdrawn.

The amendments presented herein also further distinguish Applicants' invention from the device taught by Bahl. For example, with regard to claim 5, the present amendment deletes reference to cellulose. As amended, the claim only recites a collection pad comprising glass fiber. A collection pad including glass fiber is not taught by Bahl. Accordingly, for the foregoing reasons, Applicants submit that none of the claims (either prior to or after entry of the present amendments) are anticipated by Bahl. Therefore, Applicants respectfully request entry of this Amendment, withdrawal of this rejection, and allowance of the rejected claims.

Rejection Under 35 U.S.C. 103

In the Office Action, claims 2, 3, 6, 9, 11, and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl. More specifically, the Office Action asserted that:

> With respect to the above mentioned claims, Applicants claimed that the fluid being collected is urine, the analyte being tested is albumin, and BSA as a pretreatment agent. Applicants also claim that the device has a plurality of collection pads and apertures.
>
> With respect to Applicants' claim that the device is used for collecting urine and testing for albumin, these are Applicants' intended uses for the device. Since the claims are directed to the device, per se, and not a method of using it, the intended use is not accorded patentable weight. Furthermore, although Bahl et al '160 disclose the use of the device for oral fluids, and not urine, it would have been obvious to one of ordinary skill in the art that the device is suitable for use in collecting urine samples to test for albumin

(which is commonly tested for in urine), by preserving the urine samples with BSA. This is conventional and well known in the art.

With respect to the device containing a plurality of apertures and collection pads, it would have been obvious to one of ordinary skill in the art to incorporate multiple apertures and collection pads so that multiples test or assays may be performed on a single support.

MPEP 2143 sets out the three basic criteria required for making out a prima facie case of obviousness under 35 USC 103:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

For the reasons discussed above in Applicants' response to the 102 rejection, claims 1 and 19, from which all the rejected claims 2, 3, 6, 9, 11, and 12 ultimately depend, include at least two claim elements not found in Bahl. Since a prima facie finding of obviousness requires that all claim limitations be taught or suggested by the cited reference(s) (only Bahl in this instance), Applicants submit this rejection is improper.

With reference to the individual claims, in an effort to clarify the invention, Applicants have herewith amended claims 2 and 3 to respectively recite (a) a collection pad having a biological sample comprising urine applied thereon (claim 2) and (b) a collection pad having a biological sample comprising albumin derived from urine applied thereon. Bahl does not recite a collection pad having applied thereon urine or albumin. Thus as not all the limitations of amended claims 2 and 3 are taught or suggested, amended claims 2 and 3 are patentably

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unobvious over Bahl. Entry of the Amendment and allowance of these claims is therefore respectfully requested.

Regarding claim 6, prior to entry of this Amendment, this claim included the element "polyvinyl alcohol." The Office Action did not explain the basis for this rejection; and nowhere do Applicants find a reference or suggestion to polyvinyl alcohol in Bahl. Accordingly, Applicants believe this rejection to be improper, and request it be withdrawn.

With reference to claim 9, the Office Action indicated that "... it would have been obvious to one of ordinary skill in the art that the device is suitable for use in collecting urine samples to test for albumin (which is commonly tested for in urine), by preserving the urine samples with BSA" and that "[t]his is conventional and well known in the art." Applicants respectfully disagree with this statement and submit that the Office Action's argument does not explain in reasonable detail how the prior art provides the skilled artisan the requisite suggestion or motivation to modify the teachings of Bahl to arrive at the presently claimed invention. Perhaps using the guidance provided in Applicants' disclosure, the skilled artisan might have been able to assemble the various elements of Applicants' claim 9 from Bahl and what was conventional and well known in the art- but such hindsight reconstruction is impermissible in making out a 103 rejection. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Moreover, Applicants submit that skilled artisan would have had no motivation or incentive to pretreat Bahl's pad for the following reasons.

First, contrary to the Office Action's assertion, Applicants (a) do not use BSA as a preservative and (b) do not believe the use of BSA as a preservative is either conventional or well-known in the art. As indicated in the specification at page 11, lines 14-16, Applicants use

BSA as a blocking agent to prevent irreversible binding of an analyte of interest (e.g., microalbumin) to the collection pad.

Second, Applicants point out that Bahl actually teaches away from the use of bovine serum albumin (BSA) on a collection pad. For example, as indicated above, Bahl explicitly states that his pad for collecting an oral fluid is made of medical grade 100 % pure cotton and has no chemicals or flavors added to it. Col. 3, lines 40-41 and lines 52-55. Moreover, Bahl's device is used by placing a pad into the mouth of a patient. Applicants submit that BSA is a chemical and has a flavor- a flavor that Applicants submit the skilled artisan would not generally believe desirable for introduction into a patient's mouth. Accordingly, Applicants believe this rejection to be improper, and request it be withdrawn.

Regarding the rejection of claims 11 and 12, the Office Action's argument does not explain in reasonable detail how the prior art provides the skilled artisan the requisite suggestion or motivation to modify the teachings of Bahl to arrive at the claimed invention. That is, no facts are provided supporting the Office Actions allegations. Applicants respectfully remind the Examiner that "[t]he examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness." See MPEP 2142. Accordingly, further explanation or withdrawal of this rejection is requested.

For the foregoing reasons, Applicants respectfully request entry of this Amendment, withdrawal of this rejection, and allowance of the rejected claims.

Patentability of New Claims 22-26

New claims 22-26 ultimately depend from claims 1 or 19, and are therefore believed to be patentable.

Conclusion

Applicant believes that entry of this Amendment would put the current claims in condition for allowance or in better condition for appeal. Applicant submits that the Amendment presented herein would revise the form of the claims, but would not raise additional substantive issues. Thus, no new matter would be entered by the Amendment. Accordingly, Applicant respectfully requests entry of the Amendment, and reconsideration and allowance of the claims. A clean copy of the claims as amended herein is attached as Appendix A for the Examiner's convenience.

The Commissioner is hereby authorized to charge any underpayment or credit any overpayment of fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 50-0951.

Applicants invite the Examiner to call the undersigned if clarification is needed on any matter within this Amendment, or if the Examiner believes a telephone interview would expedite

the prosecution of the subject application to completion.

Respectfully submitted,

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J. Rodman Steele, Jr.
Registration No. 25,931
Stanley A. Kim, Ph.D., Esq.
Registration No. 42,730
AKERMAN SENTERFITT
222 Lakeview Avenue, Suite 400
Post Office Box 3188
West Palm Beach, FL 33402-3188
Telephone: (561) 653-5000